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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,824	10/23/2003	Robert Burgermeister	CRD1061CIP2	6326
27777	7590	01/19/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			HOEKSTRA, JEFFREY GERBEN	
			ART UNIT	PAPER NUMBER
			3736	
DATE MAILED: 01/19/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/691,824	Applicant(s) BURGERMEISTER, ROBERT	
	Examiner Jeffrey G. Hoekstra	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-39 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-39 of copending Application No. 11/168,220. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Priority

3. It is noted that this application claims subject matter as a CIP disclosed in prior Application No. 10/224,168, filed 08/20/2002 which claims benefit of nonprovisional Application No. 60/366,739, filed 03/22/2002.

Information Disclosure Statement

4. The information disclosure statement(s) (IDS) submitted on 01/26/2004 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Drawings

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the elongated deflection member extending through and beyond the proximal end of the control handle must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 16-18, and 26-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Imran et al (5908405). For claims 1, 16, and 26, Imran et al discloses a steerable balloon catheter 71 comprising: an inner flexible tube 86 an outer flexible tube 73 defining an inner lumen 76 between said inner and outer tubes, an inflatable balloon 96 mounted on said outer tube and communicating with said inner lumen, a flexible helical coil 101 disposed about the distal portion of said flexible tubing, a tapered elongated deflection member 78 slidably disposed within said tubing and helical coil wherein the distal portion is flattened forming a deflection ribbon extending in a plane and having a proximal circular cross section (column 7 lines 3-9), a retaining ribbon 111 disposed about the distal region of the flexible tubing and oriented in a plane parallel to that of the deflection ribbon, and an attachment member 103 engaging the distal end of the helical coil, the deflection member and the retaining ribbon wherein longitudinal movement (push or pull) of the deflection member causes deflection of the distal tip in two opposing directions (column 11 lines 26-30).

8. For claims 2, 17, and 27, Imran et al discloses said retaining and deflection ribbons having a normally biased arcuate configuration thereby curving the distal end of said guiding wire for balloon catheter placement (column 12 lines 7-13).

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9. For claims 3 and 4, Imran et al discloses a steerable balloon catheter comprising a tapered elongated deflection member 78 extending from the proximal portion to approximately the distal portion of said inner tubing and having a circular cross section (column 7 lines 3-9) and further comprising a retaining ribbon 111 extending from the distal region of the flexible tubing to approximately the distal end of said flexible helical coil.

10. For claims 5 and 18, Imran et al discloses a steerable balloon catheter wherein said attachment member 103 takes a rounded ball shape (column 7 lines 28-31).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 6-10, 19-22, 28-32, and 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imran et al in view of Schaer et al (5882333). For claim 6, Imran et al discloses the claimed steerable balloon catheter except for the attachment member shaped as a rounded bead formed with a suitable adhesive, e.g. epoxy. Schaer et al teaches a steerable catheter 10 using suitable adhesive or epoxy for forming the attachment member 35 (column 5 lines 43-47). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of

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utilizing a biocompatible adhesive rather than a weld to fixably secure distal elements of the guidewire.

13. For claim 28, Imran et al discloses the claimed steerable balloon catheter except for the retaining ribbon having a circular cross section wherein the distal portion is flattened. Schaer et al teaches a steerable catheter comprising a retaining ribbon 31,64 with a flattened distal portion as best seen in Figures 2 and 5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the distal portion of the guidewire for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature

14. For claims 7, 19, and 29, Imran et al discloses the claimed steerable balloon catheter except for the deflection ribbon engaging the rounded bead attachment member at a location offset the center of the circular surface created by the engagement of the coil with the attachment member. Schaer et al teaches the engagement of a deflection member 32,65 at a location offset the center of said attachment member as best seen in Figures 2, 5, and 21. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the distal portion of the guidewire for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature.

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15. For claims 8, 20, and 30, Imran et al discloses the distal end of said retaining ribbon engaging said rounded bead attachment member at a location offset the center of said attachment member as best seen in Figure 6.

16. For claims 9, 21, and 31, Imran et al discloses the claimed steerable balloon catheter, including the distal end of said retaining ribbon engaging said rounded bead attachment member at a location offset the center of said attachment member, except for the deflection ribbon engaging the rounded bead attachment member at a location offset the center of the circular surface created by the engagement of the coil with the attachment member and in an opposite direction than the retaining ribbon. Schaer et al teaches, using incorporated reference Nitzsche (5190050), the engagement of retaining ribbon 48 and deflection ribbon 52 to the attachment member in opposite directions offset from the center of said attachment member as best seen in Figures 5 and 6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the distal portion of the guidewire for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature.

17. For claims 10, 22, and 32, Imran et al discloses the claimed steerable balloon catheter, including the engagement of a deflection member and retaining ribbon within said attachment member, except for the joining of the retaining and deflection ribbons within the rounded bead attachment member. Schaer et al teaches the joining of the deflection and retaining ribbons (column 5 lines 44-49) as best seen in Figure 9. It would have been obvious to one having ordinary skill in the art at the time the invention

was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the distal portion of the guidewire for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature and to shape the distal end of the guidewire prior to insertion.

18. For claims 36-39, Imran et al discloses the claimed steerable balloon catheter except for the control handle coupled to the flexible tubing with a release mechanism and also coupled to the deflection member which extends the entire length of and proximally beyond the handle including movable knob coupled to the deflection member for longitudinal positioning. Schaer et al teaches a control handle 14 coupled to the flexible tubing 11 including a release mechanism for said coupling and also coupling to the deflection member 32 extending the length of and beyond the handle proximally wherein said control handle comprises a movable knob 48 coupled to the deflection member for longitudinal positioning. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al, with Schaer et al for the purpose of configuring the proximal portion of the balloon catheter for ease of and enhanced control over distal bi-directional deflection means for navigating tortuous vasculature.

19. Claims 11-15, 23-25, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imran et al in view of Schaer et al and in further view of Bagaoisan et al (6355016). For claims 11, 12, 23, 24, and 33, Imran et al and Schaer et al disclose the claimed steerable balloon catheter except for the deflection and retaining ribbons formed as a single unitary element forming a generally U-shaped configuration with a

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predetermined spacing therein causing the two opposing sides to be parallel.

Bagaoisan et al teaches a deflection/retention member 120 formed as a single unitary element with a generally U-shaped configuration, a predetermined spacing therein causing the two opposing sides to be parallel as best shown in Figure 4. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al and Schaer et al, with Bagaoisan et al for the purpose of configuring the distal portion of the balloon catheter for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature, to shape the distal end of the guidewire prior to insertion, and to reduce the amount of material needed to form said apparatus.

20. For claims 13-15 and 34-35, Imran et al and Schaer et al disclose the claimed steerable balloon catheter except for the flattening of intermediate and distal portions of the deflection member to create both deflection and retaining ribbons wherein the thickness of the flattened most distal region, the retaining ribbon equal to about 0.0015 inches, is less than the thickness of the flattened intermediate region, the deflection ribbon equal to about 0.002 inches. Bagaoisan et al teaches a deflection/retention member 120 distally tapered wherein the thickness of the intermediate portion, the deflection ribbon, is greater than that of the most distal portion, the retaining ribbon, and flattened to a thickness of approximately 0.002 inches inherently capable of increased flattening. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the steerable balloon catheter as taught by Imran et al and Schaer et al, with Bagaoisan et al for the purpose of configuring the distal portion

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of the balloon catheter for enhanced control over distal bi-directional deflection means for navigating tortuous vasculature, to shape the distal end of the guidewire prior to insertion, and to reduce the amount of material needed to form said apparatus.

21. For claim 25, Imran et al discloses a steerable balloon catheter wherein said attachment member 103 takes a rounded ball shape (column 7 lines 28-31).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JGH

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